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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,277	11/14/2003	Minas Thcodore Coroneo	21800-005001	7510

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EXAMINER

HAND, MELANIE JO

ART UNIT	PAPER NUMBER
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3761

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/712,277

Applicant(s)

CORONEO, MINAS THEODORE

Examiner

Melanie J. Hand

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 22-26 is/are pending in the application.
- 4a) Of the above claim(s) 10-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 22-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/26/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 18, 2007 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1-9 have been considered but are moot in view of the new ground(s) of rejection.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on January 26, 2007 was filed after the mailing date of the final Office action on July 27, 2006. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support in the disclosure as originally filed for a valve that is coupled to the claimed drainage tube.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-8 and 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong et al (U.S. Patent No. 5,443,505).

With respect to **claim 1**: Wong teaches a flexible ocular device for implantation into the eye formed of a biocompatible elastomeric material (Col. 3, lines 47,48,64-66), foldable to a diameter of 1.5 mm or less (Col. 3, lines 9-12), comprising a fluid drainage tube having at one end a foldable plate adapted to be deployed within a suprachoroidal space and to locate the device on the inner surface of the sclera in the suprachoroidal space formed by cyclodialysis (Col. 2, lines 37-42, Col. 3, lines 6-13, Col. 12, lines 37-42, Col. 13, lines 5-10), said drainage tube opening into the suprachoroidal space and onto the plate near one end and opening to the

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anterior chamber when implanted into the eye at its other end (Fig. 1, Col. 13, lines 36,37), so as to provide aqueous pressure regulation.

With respect to **claim 2**: The fluid drainage tube has a diameter selected to control the drug concentration in the eye, which is accomplished in part by also providing predetermined resistance to aqueous flow.

With respect to **claim 3**: Wong does not teach a particular resistance, however since the structure of the device of Wong is substantially identical to the claimed invention, serves a substantially identical purpose and is placed in the suprachoroidal space wherein normal ocular pressure is 8-20 mmHg, as noted by applicant, the device of Wong is considered herein to inherently provide a resistance that falls within the range set forth in claim 3. The burden is herein upon applicant to show that the device of Wong does not provide a resistance that falls within said claimed range of 10 mm Hg or less.

With respect to **claim 6**: The plate has an equivalent diameter of 0.56 mm which falls within the range set of from 0.05 to 6 mm, and a thickness of 0.25 – 1 mm, which overlaps the range of from 12.5 microns to 250 microns. (Col. 10, lines 11-20)

With respect to **claim 7**: Wong teaches that when the device is in fiber form, its length is between 0.5-5 mm, wherein the length of the tube is a fraction of that length thus the drainage tube will have a length equal to or less than 0.5-5 mm so as to ensure proper sizing and function of the tube. The range overlaps the range claimed in claim 7.

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With respect to **claim 8**: The tube comprises an outer diameter of 0.1-1 mm or 100-1,000 microns, which overlaps the range of 400-1000 microns. Wong teaches a thickness for the sheet for ease of handling, the thickness of the tube would be within the range as well and the tube would have an inner diameter that would necessarily overlap the range of from 50 to 500 microns.

With respect to **claim 22**: Wong teaches an ocular device for implantation into the eye, comprising: a fluid drainage tube having at a first end an anchor member adapted to be deployed within a suprachoroidal space on an inner surface of the sclera so as to locate the first end of the device on an inner surface of the sclera (Col. 2, lines 37-42, Col. 3, lines 6-13, Col. 12, lines 37-42, Col. 13, lines 5-10), wherein the first end of the drainage tube opens into the suprachoroidal space and a second end of the drainage tube opens into the anterior chamber when implanted into the eye (Fig. 1, Col. 13, lines 36,37), so as to provide aqueous pressure regulation.

With respect to **claim 23**: The anchor member is a disc. ('505, Col. 10 , lines 11-13)

With respect to **claim 24**: The device is formed of a biocompatible elastomeric material. (Col. 3, lines 47,48, 64-66)

With respect to **claim 25**: The device is flexible and has a diameter of 0.5 mm and is considered herein to be foldable to a diameter of 1.5 mm or less. (Col. 3, lines 9-12, Col. 10, lines 16-18)

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4,5,9 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong ('505) in view of Mitrev (U.S. Patent No. 6,589,203).

With respect to **claim 4**: Wong does not teach that said fluid drainage tube contains a valve so as to regulate pressure of the aqueous at a predetermined level. Mitrev teaches a glaucoma drainage device implant having a valve. Mitrev teaches that the valve limits the flow of aqueous fluid through the drainage tube when the pressure exerted thereon is below a predetermined pressure threshold ('203, Col. 2, lines 42-45), therefore it would be obvious to modify the device of Wong so as to include a valve for the drainage tube as taught by Mitrev so as to limit drainage flow when the pressure on the valve has fallen below a desired value.

With respect to **claim 5**: The combined teaching of Wong and Mitrev does not teach said predetermined level, however since normal ocular pressure varies between 8-20 mmHg, it would be obvious to one of ordinary skill in the art to set the predetermined level of the combined teaching of Wong and Mitrev to be less than 8 mmHg to prevent a lack of sufficient pressure due to overdrainage. This range of less than 8 mmHg falls within the range set forth in claim 5. The motivation to combine the devices of Wong and Mitrev has been stated supra with respect to claim 4.

With respect to **claim 9**: Mitrev teaches that the valve comprises a slit valve inasmuch as the valve allows aqueous humor to drain through the drainage tube. ('203, Col. 2, lines 42-45) The

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motivation to combine the devices of Wong and Mitrev has been stated supra with respect to claim 4.

With respect to **claim 26**: Wong does not teach a valve coupled to the drainage tube. Mitrev teaches a valve that is contained within the tube. Thus the combined teaching of Wong and Mitrev renders claim 26 unpatentable. The motivation to combine the teachings of Wong and Mitrev has been addressed supra with respect to claim 4.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand

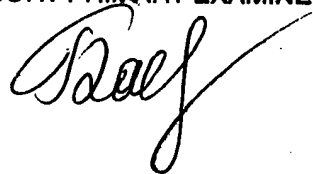
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March 21, 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Tatyana', written over the printed name and title.